PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BABY'S OWN COUGH SYRUP (45,52 mg/5 ml; syrup)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syrup contains:

Ammonium chloride	45,52 mg
Preservatives:	
Methylparaben (methyl hydroxybenzoate)	2,49 mg (0,05 % *m/v*)
Benzoic acid	0,521 mg (0,01 % *m/v*)

Contains sugar: 1,87 g glucose and 2,80 g sucrose per 5 ml.

Contains camphor (flavourant): 0,521 mg per 5 ml (0,008 % *w/w*).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrups

BABY'S OWN COUGH SYRUP is a red syrupy liquid.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

BABY'S OWN COUGH SYRUP is indicated for the temporary relief/alleviation of cough.

4.2. Posology and method of administration

Posology

Shake well before use.

Doses must be taken with an adequate amount of fluid (half to one glass).

Children:

2 to 6 years: 7,5 ml every 2 to 4 hours in water.

6 to 12 years: 15 ml every 2 to 4 hours in water.

Adults:

15 ml to 30 ml every 2 to 4 hours in water.

Method of administration

Doses must be taken orally.

4.3. Contraindications

- Hypersensitivity to ammonium chloride or any of the ingredients of BABY'S OWN COUGH SYRUP (see section 2 and section 6.1).
- BABY'S OWN COUGH SYRUP is contraindicated in patients with hepatic or renal impairment.

4.4. Special warnings and precautions for use

WARNING:

Contains CAMPHOR (as flavourant). Use only as directed – excess quantities may be harmful if swallowed. Advise users to keep out of the reach of children.

Persistent coughs should be investigated for possible underlying cause by the patient's doctor.

Liquorice may cause reversible sodium retention and potassium loss leading to hypertension, water retention and electrolyte imbalance.

Use with caution in patients with heart disease.

BABY'S OWN COUGH SYRUP contains camphor as flavourant. Avoid use in pregnancy (see section 4.6), epilepsy, and chronic lung conditions. Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

BABY'S OWN COUGH SYRUP contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BABY'S OWN COUGH SYRUP.

BABY'S OWN COUGH SYRUP contains glucose (1,87 g per 5 ml) and sucrose (2,80 g per 5 ml) which may have an effect on the glycaemic control of patients with diabetes mellitus.

BABY'S OWN COUGH SYRUP contains 0,521 mg benzoic acid in each 5 ml dosage unit which is equivalent to 0,1 mg/ml. Benzoic acid may increase jaundice in newborn babies (up to 4 weeks old). Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue). BABY'S OWN COUGH SYRUP should therefore not be used in children under 2 years of age.

BABY'S OWN COUGH SYRUP contains Carmoisine CI 14720 as colourant that may cause allergic reactions.

4.5. Interactions with other medicines and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, pregnancy, and lactation

The safety of this preparation in pregnancy and lactation has not been established.

BABY'S OWN COUGH SYRUP contains camphor and use in pregnancy should be avoided (see section 4.4).

4.7. Effects on ability to drive and use machines

Large doses of BABY'S OWN COUGH SYRUP may cause drowsiness and interfere with the ability to drive or use machinery.

4.8. Undesirable effects

Possible side effects include:

Metabolism and nutrition disorders

*Frequency unknown:** Acidosis and hypokalaemia

(*Cannot be reliably estimated from available data)

Nervous system disorders

Frequency unknown: Headache, progressive drowsiness

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Hyperventilation

Gastrointestinal disorders

Frequency unknown: Nausea and vomiting

General disorders and administrative site conditions

Frequency unknown: Thirst

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Side effects may also be reported to Mentholatum Customer Care at www.mentholatum.co.za.

4.9. Overdose

Large doses of BABY'S OWN COUGH SYRUP may cause nausea, vomiting, thirst, headache, abnormally deep and rapid breathing and progressive drowsiness, gastric irritation, acidosis and hypokalaemia. If the capacity of the liver to convert ammonium ion to urea is exceeded, hepatic encephalopathy may ensue.

Large doses of camphor may cause nausea, vomiting, dizziness, colic, headache, a feeling of warmth, delirium, muscle twitching, recurrent fits, depression of the

central nervous system and coma. Breathing is difficult and the breath has a characteristic odour; anuria may occur.

Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A 10.1 Antitussives and expectorants.

Pharmacotherapeutic group: Other cough suppressants and expectorants

ATC code: R05FB02

Expectorants are considered to increase the volume of secretions in the respiratory tract thereby facilitating their removal by ciliary action and coughing, achieved by a reflex irritant effect on the gastric mucosa.

5.2. Pharmacokinetic properties

Ammonium chloride is absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver. The anion is thus liberated into the blood and extracellular fluid causes a metabolic acidosis and decrease the pH of the urine. This is followed by transient diuresis.

5.3. Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Anise oil

Benzoic acid (preservative)

Camphor

Carmoisine C/I No 14720 (colourant)

Clark's Caramel C/I No 4800

Glacial acetic acid

Liquid glucose

Liquorice liquid extract

Methyl hydroxybenzoate (methylparaben) (preservative)

Purified water.

Strong ammonia solution 25 %

Syrup simplex (sucrose)

6.2. Incompatibilities

None known.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 °C and protect from light.

6.5. Nature and contents of container

BABY'S OWN COUGH SYRUP is filled into 50 ml, 100 ml or 200 ml round amber glass bottles. The bottles are closed with a polypropylene cap.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

None.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Mentholatum South Africa (Pty) Ltd

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Steenberg Office Park

Silverwood Close

Tokai

7945

8. APPLICATION NUMBER(S):

G600 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 November 2019

10. DATE OF REVISION OF THE TEXT

29 September 2025